IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Zilla et. al**		
Serial No.:	**10/627,114**	**Group Art Unit:**	**3738**
Filed:	**07/25/2003**	**Examiner:**	**D. Willse**
For:	**Transmural Concentric Multilayer Ingrowth Matrix Within Well-Defined Porosity**	**Confirmation:**	**3869**

BRIEF FOR APPLICANTS

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BRIEF FOR APPLICANTS

This is an appeal from the final rejection of the above-identified application made in the Office action mailed June 30, 2008. A Notice of Appeal was mailed on December 29, 2008.

I. REAL PARTY IN INTEREST

The real party in interest in connection with the present appeal is Medtronic, Inc., owner of a 100 percent interest in the pending application.

II. RELATED APPEALS AND INTERFERENCES

The Applicants are unaware of any pending appeals or interferences which may directly affect or be directly affected by, or have a bearing on, the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 71-87 and 103-105 are pending in this application. In the Final Office action of June 30, 2008, claims 71-87 and 103-105 stand finally rejected. The rejection of claims 71-87 and 103-105 is appealed.

IV. STATUS OF AMENDMENTS

No amendments have been filed after the Final Office action of June 30, 2008.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 71 is directed to a prosthetic material[1] including a scaffold[2] having interconnecting, uniformly shaped pores[3], and an ingrowth matrix within the pores[4], wherein the ingrowth matrix comprises a concentration gradient of a material[5] and is adapted to promote ingrowth of tissue in the scaffold.[6] Varying concentrations within the ingrowth matrix are designed to perform specific functions.[7]

Claim 82, which depends from claim 71, recites a scaffold including interconnecting, helically oriented channels within the scaffold.[8]

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

This is an appeal from the final rejection of:

1) Claims 71, 72, 74, 77, 78, 84 and 103-105 under 35 U.S.C. § 102(a) as allegedly being anticipated by Starling[9], and

2) Claims 71-87 and 103-105 and 20 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Starling. The claims on appeal are set forth in full in the Appendix to this Brief.

VII. ARGUMENT

A. REJECTIONS UNDER 35 U.S.C. § 102(a)

a. CLAIMS 71, 72, 74, 77, 78, 84 AND 103-105

Claims 71, 72, 74, 77, 78, 84 and 103-105 stand rejected under 35 U.S.C. § 102(a) as

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1 See Applicant's Specification, page 5, line 16.
2 See Id., page 5, line 17.
3 See Id., page 5, lines 18-19.
4 See Id., page 5, line 18-19.
5 See Id., page 9, lines 1-2, Figure 4.
6 See Id., page 9, lines 9-10.
7 See Id., page 9, lines 7-8.
8 See Id., page 5, line 19, Figure 5.
9 PCT Application WO 98/43558

being anticipated by Starling.[10] The Applicants respectfully disagree.

Starling is directed to calcium phosphate microcarriers and microspheres for use, among other things, as implantable materials useful for biomedical implants. The microspheres can be aggregates of hollow microspheres having dense walls.[11] The microspheres can be used as carriers of growth factors or pharmaceutical agents.[12] The growth factor or pharmaceutical agent can either be coated on the microsphere, impregnated within the wall of the microsphere, or be located in a central cavity of the microsphere.[13] The wall of the microsphere can be replaced by tissue in-growth as material within the wall resorbs.[14]

M.P.E.P. §2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

In the present invention, independent claim 71 requires an ingrowth matrix within the pores of the scaffolding, wherein the ingrowth matrix comprises a concentration gradient of a material and is adapted to promote ingrowth of tissue in the scaffold. Varying concentrations within the ingrowth matrix are designed to perform specific functions.

An exemplary description of this feature of the present invention states:

> More specifically, one material is present throughout the ingrowth matrix 27, but in various concentrations between a core of the ingrowth matrix 27 and an outermost surface of the ingrowth matrix 27. Like the layers 28, 30 and 32 in the multilayered embodiment, the concentration gradient 38 is present throughout the transmural ingrowth channels 34 and/or pores 36. Furthermore, varying concentrations within the ingrowth matrix 27 are designed to perform specific functions. For example, different cells can be sensitive to different concentrations, therefore a concentration gradient allows multiple ingrowth options within one matrix 27.[15]

The Applicants respectfully submit that Starling lacks, among other things, a teaching or suggestion of the ingrowth matrix as claimed, specifically an ingrowth matrix within the scaffold having a concentration gradient of a material that is adapted to promote ingrowth of tissue in the

10 Office action, dated January 19, 2005, at page 2, last paragraph.
11 See PCT Application WO 98/43558, Figure 1.4.
12 See Id., page 13, lines 11-13.
13 See Id., page 13, lines 17-24.
14 See Id., page 13, lines 26-28.
15 Applicants' Specification, page 9, lines 13-21.

scaffold, wherein varying concentrations within the ingrowth matrix are designed to perform specific functions.

The Applicants respectfully submit that the ingrowth matrix described in Starling does not have varying concentrations designed to perform specific functions as claimed in independent claim 71. The Examiner states:

> Starling . . . discloses a . . . concentration gradient of growth factors or other pharmaceutical agents(page 13, lines 15-17 and 23-24; page 33, lines 10-14 and 26-27), wherein the varying concentrations within the aggregate or ingrowth matrix (page 13, lines 26-31) are designed to perform the specific function of driving the sustained diffusion and release of growth factors, anti-inflammatory agents, and/or anti-tumor agents (page 13, lines 11-13).[16]

The Applicants respectfully submit that the cited passages from Starling do not disclose concentration gradients of materials wherein varying concentrations within the ingrowth matrix are designed to perform specific functions. The cited passages of Starling disclose only that "open porosity [of the microspheres] can be adjusted to facilitate delivery of specific biological growth factors and pharmaceutical agents"[17]; "[h]ollow microspheres and hollow microspheres bonded in aggregate provide a central cavity as a reservoir for growth factors or other pharmaceutical agents"[18]; and "the thin wall of the hollow microsphere can be replaced by tissue in-growth as the material within the wall resorbs"[19]. Starling also discloses that the degree of resorbability of the wall can be adjusted by designing the wall to have specific physical or chemical characteristics.[20] Additionally, the Examples of Starling as referenced by the Examiner disclose only that the "microspheres are placed in a solution containing transforming growth factor – beta to infiltrate and coat the microspheres with the growth factor. . . . The amount of growth factor can be increased by infiltrating under vacuum."[21] The Applicants respectfully submit that the ingrowth matrix described in Starling does not have varying concentrations designed to perform specific functions. Starling is absolutely silent as to any design including a concentration gradient of a material or a resulting gradient that would involve one concentration

16 Office action, dated June 30, 2008, at page 2, last paragraph.
17 PCT Application WO 98/43558, page 13, lines 15-17.
18 Id., page 13, lines 23-24.
19 Id., page 13, lines 26-28.
20 See Id., page 13, lines 28-31.
21 Id., page 33, lines 11-14.

having any specific function over another.

Claims 72, 74, 77, 78, 84 and 103-105 depend on and incorporate all of the limitations of independent claim 71.

For at least the reasons discussed herein above, Applicants respectfully submit that claims 71-72, 74, 77, 78, 84, and 103-105 are neither taught nor suggested by Starling.

Reconsideration and withdrawal of the rejections under 35 U.S.C. 102(a) are respectfully requested.

B. REJECTIONS UNDER 35 U.S.C. § 103(a)

a. CLAIMS 71-81, 83-87 AND 103-105

Claims 71-81, 83-87 and 103-105 stand rejected under 35 U.S.C. § 103(a) as being obvious over Starling.[22] The Applicants respectfully disagree.

M.P.E.P. §706.02(j) states, "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure." As discussed above, however, technically and commercially significant features of the presently-claimed inventions are not taught or suggested by the prior art.

As discussed above, the Applicants respectfully submit that Starling fails to teach or suggest certain features of the rejected claims, including an ingrowth matrix having a concentration gradient of a material that is adapted to promote ingrowth of tissue in the scaffold where varying concentrations within the ingrowth matrix are designed to perform specific functions. For at least this reason, Applicants assert that independent claim 71 is not obvious over Starling.

Additionally, the Applicants respectfully submit that a skilled artisan would not have arrived at the invention defined by claim 71 based on the disclosure of Starling. Specifically, the

22 Office action, dated June 30, 2008 at page 3.

presently-claimed invention –requiring an ingrowth matrix having a concentration gradient of a material that is adapted to promote ingrowth of tissue in the scaffold where varying concentrations within the ingrowth matrix are designed to perform specific functions– is not disclosed by Starling either expressly or inherently.

As discussed above, the Applicants' claims are directed to a prosthetic material, such as a vascular graft, having a concentration gradient of materials in an ingrowth matrix within well-defined pores and/or channels within the prosthetic. Each concentration of the matrix is designed to perform a specific function. For example, one concentration can be designed for facilitation of ingrowth of endothelial cells, a second concentration can contain adhesive and degradation sites that allow for optimal ingrowth of smooth muscle cells and a third concentration can be designed to modify a surface of the scaffold material for macrophage pacification. Thus, the Applicants' claims are focused on and directed to prosthetic materials having ingrowth matrices designed to promote specific and varying ingrowth, which is not typical for scaffold materials containing ingrowth materials. The device of Starling utilizes growth factors which promote ingrowth, but are not intended to create ingrowth of different or varying materials by design of an ingrowth matrix. Thus, one of ordinary skill in the art would not arrive at the present invention defined by the claims by looking to Starling.

Claims 72-81, 83-87 and 103-105 depend directly or ultimately from independent claim 71. Applicants respectfully submit that claims 72-81, 83-87 and 103-105 are patentable over Starling for at least the reasons discussed herein above for the patentability of claim 71, in addition to reasons related to the additional subject matter recited in each.

Reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a) are respectfully requested.

c. CLAIM 82

Claim 82 stands rejected under 35 U.S.C. § 103(a) as being obvious over Starling.[23] The Applicants respectfully disagree. Claim 82, which depends upon and incorporates all of the limitations of claim 71, requires that the scaffold have interconnecting, helically oriented channels within the scaffold. Starling does not teach this feature. Starling does teach a thread of

23 Office action, dated June 30, 2008, at page 3.

a bone screw having a helical design. However, this is not what is claimed. The screw thread disclosed in Starling does not constitute interconnecting helical channels within the scaffold of the prosthesis, but rather a single helical feature on the outer surface of a device. For at least this reason, claim 82 is not obvious over Starling.

Reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a) are respectfully requested.

VIII. CONCLUSION

For the foregoing reasons, the Applicants respectfully submit claims 71-87 and 103-105 are patentable over the art of record and request that the rejection of these claims as being unpatentable be reversed.

The Commissioner is hereby authorized to charge the fees required in connection with this Brief to Deposit Account No. 13-2546, in accordance with the Transmittal submitted herewith. The Commissioner is also authorized to debit any other fees required in connection with this application, or to credit any overpayment of fees in connection with this application to Deposit Account No. 13-2546.

Respectfully submitted,

Date Submitted: 7-28-2009

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CLAIMS APPENDIX

Claims 1-70 (canceled)

71. (Previously presented) A prosthetic material comprising:

a scaffold having interconnecting, uniformly shaped pores; and

an ingrowth matrix within the pores, wherein the ingrowth matrix comprises a concentration gradient of a material, and is adapted to promote ingrowth of tissue in the scaffold and wherein varying concentrations within the ingrowth matrix are designed to perform specific functions.

72. (original) The prosthetic material of Claim 71 wherein the material in the concentration gradient comprises a synthetic material.

73. (original) The prosthetic material of Claim 72 wherein the synthetic material comprises a hydrogel.

74. (original) The prosthetic material of Claim 71 wherein the material in the concentration gradient comprises a protein.

75. (original) The prosthetic material of Claim 74 wherein the protein is selected from the group consisting of fibrin, collagen, glycosaminoglycan, and combinations thereof.

76. (original) The prosthetic material of Claim 71 wherein the material in the concentration gradient comprises a protein and a synthetic material.

77. (original) The prosthetic material of Claim 71 wherein the material in the concentration gradient comprises a growth factor.

78. (original) The prosthetic material of Claim 71 wherein the material in the concentration gradient

comprises a peptide.

79. (original) The prosthetic material of Claim 71 wherein the concentration gradient comprises a delivered gene.

80. (original) The prosthetic material of Claim 71 wherein the concentration gradient comprises a fibrin matrix.

81. (original) The prosthetic material of Claim 71 wherein the concentration gradient comprises a polyethylene glycol matrix.

82. (original) The prosthetic material of Claim 71 further comprising interconnecting, helically oriented channels within the scaffold.

83. (original) The prosthetic material of Claim 71 wherein substantially all of the pores have diameters within 300 μm of one another.

84. (previously presented) The prosthetic material of Claim 71 wherein the pores have the shape of a sphere.

85. (original) The prosthetic material of Claim 71 comprising a vascular graft.

86. (original) The prosthetic material of Claim 71 comprising a sewing ring.

87. (original) The prosthetic material of Claim 71 comprising a synthetic heart valve.

Claims 88-102 canceled.

103. (previously presented) The prosthetic material of claim 71, wherein one material is present throughout the ingrowth matrix of each pore in various concentrations between a core of the

ingrowth matrix and an outermost surface of the ingrowth matrix.

104. (previously presented) The prosthetic material of claim 71, wherein the same concentration gradient is present in each pore.

105. (previously presented) The prosthetic material of claim 71, wherein the ingrowth matrix is designed to allow multiple ingrowth options within each pore.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.